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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,018	01/15/2002	Eduardo N. Mitrani	01/22527	8957

7590 07/20/2005

c/o ANTHONY CASTORINA  
G.E. EHRLICH (1995) LTD.  
SUITE 207  
2001 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VA 22202

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/045,018	<b>Applicant(s)</b> MITRANI, EDUARDO N.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/15/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*HL*

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/09/2005 has been entered.

### ***Election/Restrictions***

Claims 1-17 and 29-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/19/2004.

Claim 19 has been cancelled. Claims 18,20-22,24-26 and 28 are amended. Claims 1-17 and 29-33 are withdrawn. Claims 1-18 and 20-33 are pending and claims 18 and 20-28 are under consideration in the instant office action.

### ***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18,23 and 25-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for repopulating a devitalized acellular three dimensional scaffold with pluripotent stem cells or progenitor cells or differentiated cells derived from the

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same tissue source as the scaffold, does not reasonably provide enablement for repopulating the scaffold with any differentiated cell type other than those derived from the same tissue source as the scaffold. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered and are not found persuasive. The rejection is maintained for reasons of record set forth on pages 2-4 of the office action dated 02/08/2005.

The claims were rejected on the grounds that the specification is not enabling for repopulating the claimed scaffold with differentiated cells of a different tissue origin than the microorganism itself. Applicant has amended the claims to read "homologous differentiated cells" in attempt to limit the claims such that they do not encompass repopulating a scaffold with differentiated cells of a different tissue origin than the scaffold. This limitation fails to overcome the rejection because the specification fails to define the term "homologous differentiated cell". The limitation does not limit the claim to cells derived from the same tissue source as the scaffold as a "homologous differentiated cell" could be interpreted as a cell from the same organism as the scaffold. It is not defined to what the term "homologous" is in relation. Therefore, due to the lack of definition of the terminology "homologous differentiated cell", the claim is not limited to progenitor cells derived from the same tissue source as the scaffold and the rejection is maintained for reasons of record.

The following new matter rejection was necessitated by amendment.

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Claims 18 and 20-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

The newly added claims contain the terminology "homologous differentiated cells" (claims 18 and 22) and "homologous progenitor cells" (claim 28). Literal support for this terminology is not found in the specification.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. **Applicant should therefore specifically point out the support for any amendments made to the disclosure**" (emphasis added).

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 22 contain the terminology "homologous differentiated cells". This term is not defined by the specification or the claims. It is not clear if the term is to be interpreted as a

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cell of the same (homologous) tissue-type origin as the scaffold in the same species of organism or a homologous tissue type from a different species of organism. Claims 20-28 depend from claim 18.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) The rejection of claims 18 and 20-28 under 35 U.S.C. 102(b) as being anticipated by Vacanti (1999) is withdrawn in light of Applicant's amendment to the claims limiting the scaffold to a tissue-derived scaffold. Vacanti taught synthetic scaffolds and did not teach tissue-derived scaffolds.

2) The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Vacanti (1998) is withdrawn in light of Applicant's amendment to the claims limiting the scaffold to a tissue-derived scaffold. Vacanti taught synthetic scaffolds and did not teach tissue-derived scaffolds.

3) The rejection of claims 18,20 and 22-28 under 35 U.S.C. 102(b) as being anticipated by Riviere is withdrawn. Applicant's arguments set forth on pages 9-11 of Applicant's response have been fully considered and are found persuasive.

It is Applicant's position that Riviere does not teach complete decellularization of a tissue scaffold and that 100% complete decellularization is being claimed. While it is held that that the term "decellularized" encompasses a great variation in the degree of decellularization (see

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Mitchell), the claims contain the limitation "acellular" which is interpreted as completely void of cells. The teachings of Riviere do not encompass a matrix completely void of cells as lethal irradiation of bone marrow does not completely devitalize the tissue and some living cells remain.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) The rejection of claims 18-24 under 35 U.S.C. 103(a) as being unpatentable over Mitchell in view of Vacanti ('417) and Vacanti ('610) is withdrawn. Mitchell did not teach using tissue-derived scaffolds of the claimed dimensions.

2) The rejection of claims 18 and 23-36 under 35 U.S.C. 103(a) as being unpatentable over Bruchman in view of Vacanti ('417) and Vacanti ('610) is withdrawn in light of Applicant's arguments.



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***Conclusion***

No claim is allowed.

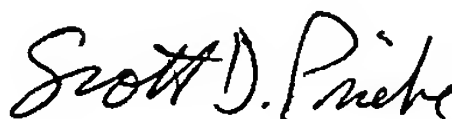
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER